REMARKS

Claims 1-13, 15-27 and 29-34 are pending.

Claim Rejections - 35 USC §103

Moroni/Scholtens et al/Loontjens et al

Claims 1-3, 5-13, and 15-16 have been rejected as obvious from Moroni (US 6,426,145) in view of Scholtens et al (DSM presentation slides, Reference CA on paper 7) and Loontjens et al (US 6,228,980). The Office Action observes that this rejection can be overcome by showing that the inventions were commonly owned at the time of the present invention. The requisite statement is provided on a separate paper filed concurrently herewith. Therefore this rejection is seen to have been obviated. Nothing in this response should be taken as an indication that the applicant has acquiesced to the rationale of this rejection.

Chen et al/Scholtens et al/Loontjens et al

Claims 1-13, 15-27, and 28-34 have been rejected as obvious from Chen et al, (US 5,5554,120) in view of Scholtens et al and Loontjens et al. The rejection is traversed.

The rationale of the rejection is quoted in detail below:

> Chen teaches that polyamides having molecular weights in excess of 5,000 can be blended with polyolefins to give compositions that produce medical devices having improved burst pressures (abstract). The compositions are used to make dilatation balloons (col. 1, line 14). Balloon tubing is made via extrusion (cal. 8, lines 6-9). The balloons made have better handling properties than PET (ccl. 7, lines 52-54).
>
> Chen fails to teach the use of the chain extended polyamides.
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> Scholtens and the Loontjens patent are discussed above.[1] Note, also, that Loontjens teaches chain extended polyamides having molecular weights of 15,000 or more at col. 5, lines 1-5.
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> The extrusion blending and reaction features of applicants' process claims are taught by Scholtens and the Loontjens patent.
>
> It would have been obvious to one having ordinary skill in the art at the time that the invention was made to

1 This is understood to refer to the following statement made earlier in the Office Action:

Scholtens teaches the use of chain extended polyamides (PA) and polyester (PET for polyethylene terephthalate) in Slide 18. The extended materials have high molecular weights that give them better mechanical properties and make them suitable as engineering plastics applications (Slide 2). The extenders are carbonyl bis-caprolactam (CBC) and 1 ,4-phenylene bisoxazoline (1,4-PBO) (Slide 8). The extenders are added during processing of the PA or PET (Slide 10), so that no extra processing step and single screw extruders can be used (Slide 6).

The Loontjens patent teaches that 1,3-PBO, CBC and N,N'-isophthaloyl biscaprolactam (IBC) are useful chain extenders for polyamides and PET (cal. 3, lines 2-15). The polyamides and polyesters made have high molecular weights (col. 1, lines 5-6). The compositions are melt mixed with the chain extenders (col. 2, lines 43) and extrusion molded to make articles (col. 5, lines 7-8). Its process gives higher molecular weight polym rs very quickly (col. 1, lines 48-52).

employ the chain extended polyamides of Scholtens and the Loontjens patent, or analogs thereof, to make the balloons of Chen in order to improve the mechanical properties of the balloons (per Scholtens) and shorten production times (per Loontiens).

The motivation to employ the chain extenders of Scholtens and Loontjens to make the balloons of Chen is found at Slide 2 of Scholtens and at cal. 1, lines 48-52 of the Loontjens patent, where improved mechanical properties and quick reaction are taught.

It is deemed desirable to make medical devices using plastics that have improved mechanical properties so to product integrity is insured when they are placed inside patients' bodies.

It is deemed desirable to make medical devices quickly to improve manufacturing efficiency and profits.

The applicant does not agree that a general representation of "improved properties" and/or "higher" molecular weights are sufficient to have motivated the skilled person in the medical device forming arts to employ the additives of Scholtens et al and Loontjens et al in the extrusion melts of Chen et al. The "improved" properties described in Scholtens et al and Loontjens et al are simply too remote from the balloon properties of Chen et al to create in the mind of the skilled person a reasonable expectation of success in improving those balloon properties.

As a general observation, the skilled person in the industry of manufacturing polymeric medical devices, at least devices such as catheters, balloons and the like, had not previously been motivated to incorporate into the polymer reactive additives which increase molecular weight during melt processing. See page 2 of the application. Radiation crosslinking of ***post-extrusion*** tubes or balloons was known, from, *e.g.* Chen, US 5,554,120, and others, but reaction in the melt stage of processing is not known to have been employed in this art. The reluctance to explore reactive systems for preparation of such devices is believed to have been due, at least in part, to the fact that reliability of device properties has traditionally had a greater importance than incremental improvements in bulk properties of starting materials.

With respect to devices which require post-extrusion thermal processing, such as Chen's balloons, as well as some stents, catheters, and the like, a substantial component of the physical properties are due to the post-extrusion thermal processing steps, including longitudinal and radial orientation, shrinking, heat-set crystallization, sterilization, and the like. Balloon properties are not those of the bulk polymer or of the extruded polymer. Extruded polymer must be subsequently processed by radial expansion (with or without additional longitudinal stretching and with/or without post-blowing heat setting or shrinking). The balloon properties are derived combination of the bulk material properties and processing features. It is not immediately apparent from anything in either Chen et al or in the Scholtens et al and Loontjens et al

documents that increased molecular weight of polymer coming out of a melt processing stage will follow through to improved device properties or overall savings in time in processing steps.

With at least some balloon materials, resistance to post-extrusion thermal processing is known even without melt-reacting the polymer with a chain extender. See discussion of WO 99/44649 at page 2, lines 15-20 of the application. Neither Scholtens et al and Loontjens et al teach anything which would have led the skilled person to expect that melt-stage molecular weight increases introduced into the Chen et al formulations would not generate similar post-extrusion processing problems.

Considerations which neither Scholtens et al and Loontjens et al address, but which a skilled person would have needed to reasonably expect success in incorporating the chain extenders of these documents into a Chen et al composition include:

Would use of chain extenders in blends restore the disadvantages which the blends are designed to ameliorate? High burst strength is one of the desired properties of a balloon, but so is good flexibility, low profile, high resistance to fatigue, low compliance and lower susceptibility to defects through mechanical handling and to pin-hole defects. Chen, Col. 2, lines 31-39. Scholtens et al and Loontjens et al do not discuss any of these.

Would use of chain extenders in blends change the relative compatibility property properties of the blend? Chen is very concerned with compatibility. Scholtens et al and Loontjens et al do not discuss compatibility.

Several components of Chen et al's blend are reactive with the chain extender. Will the crosslinker react preferentially with one or another? Is that beneficial or harmful? If it reacts with both, does the resulting polymer product have new properties as a graft or block copolymer that are material to device performance? Scholtens et al and Loontjens et al do not discuss cross-reaction between multiple polymer components.

What does the chain extension do to post-extrusion processing? Again, Scholtens et al and Loontjens et al do not discuss whether increased molecular weight at the extrusion stage will make the extruded parisons more difficult to process into balloons.

The absence of information in Scholtens et al and Loontjens et al, regarding properties obtained by chain extension which are directly relevant to those desired by Chen et al negates

prima facie obviousness.

Moreover, Chen et al, does not suggest that molecular weights are deficient. In fact, the combination of properties desired in Chen's balloons include at least some properties which could reasonably have been expected to be compromised as molecular weight of the polymer material is increased. Chen reports that balloons made from PET are stiff and not readily refoldable and susceptible to acquiring defects from mechanical handling. Col. 2, lines 8-10. Chen proposes blends of a first crystalline polymer component and a second softening component, and sometimes a compatibilizing component. Col. 2, lines 52-61. It is submitted that Chen's need for a softening component is more likely to motivate experiments directed to ***reduction*** in molecular weight of the first polymer than it is to cause a person of skill in the art to believe that the balloon properties could be improved by introducing a molecular weight increasing chain extender into the composition. Thus, at least indirectly, Chen is seen to teach away from the obviousness of including a component which causes polymer molecular weight increases. Inclusion of the chain extenders of Scholtens et al and Loontjens et al in a Chen et al composition is not *prima facie* obvious for the additional reason that the increased molecular weight would reasonably be expected to counter-act at least some of the desired benefit of Chen et al's softening polymer.

Prima facie obviousness requires that the asserted motivation or suggestion provide the hypothetical skilled person with a reasonable expectation of success. "Obvious-to-try" is not the standard. *In re Dow Chemical Co.*, 837 F.2d, 469, 473, 5 USPQ2d 1529, 1532 (Fed. Cir. 1985); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380, 231 USPQ 81, 90-91 (Fed. Cir. 1986), *cert. denied*, 107 S.Ct. 1606 (1987); *Jones v. Hardy*, 727 F.2d 1524, 1530, 220 USPQ 1021, 1026 (Fed. Cir. 1984); *In re Tomlinson*, 363 F.2d 928, 931, 150 USPQ 623, 626 (CCPA 1966). In the present case, an objective view of the cited documents, without impermissibly referring in hindsight to our knowledge of applicant's success, demonstrates that the cited documents do not collectively contain the information which would be necessary to generate a reasonable expectation of success.

Finally, the assertion that Loontjens et al's teaching of quick reaction confers a general motivation to employ its chain extenders is also traversed. Motivation to increase speed in manufacturing of ***devices*** is not seen to be generated by this document. Loontjens et al is talking

about speed of manufacturing ***polymer*** (Abstract). Manufacture of polymers is not a step in Chen et al's process. Commercial polymers are used in Chen et al's extrusions. No time will be saved by adding a chain extender to Chen et al's extrusion. To the contrary, some incremental amount of time will be added to Chen's process to incorporate the chain extender into the melt composition of the extruder. Therefore this assertion is also not well taken.

Conclusion

The obviousness rejection on Moroni in view of Scholtens et al and Loontjens et al has been obviated. The obviousness rejection on Chen et al in view of Scholtens et al and Loontjens et al has been overcome. No other issues are seen to be outstanding. The application is therefore believed to be in condition for allowance. Early and favorable action thereon is respectfully requested.

Respectfully submitted,

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